DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 7 1988

Re: Novantrone
Docket No. 88E-0067

SOLICITOR

MAR 11

U.S. PATENT AND TRADEMARK OFFICE

#20

Charles E. Van Horn, Esq.
Deputy Solicitor, Solicitor's Office
U.S. Patent and Trademark Office
Washington, D.C. 20231

Dear Mr. Van Horn:

This is in regard to the application for patent term extension for U.S. Patent No. 4,278,689 filled by the American Cyanamid Company under 35 U.S.C. 156. The human drug claimed by the patent is Novantrone (mitoxantrone hydrochloride), New Drug Application (NDA) 19-297.

A review of the Food and Drug Administration's official records confirms that Novantrone was subject to a regulatory review period before commercial marketing or use, as required under 35 U.S.C. 156(a)(4). Our records also indicate that NDA 19-297 represents the first commercial use or marketing of the active ingredient, mitoxantrone hydrochloride. The NDA was approved on December 23,1987 which makes the submission of the patent term extension application on February 17, 1988 timely within 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A), we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)

cc: Alphonse R. Noe, Manager
Patent Law Department
AMERICAN CYANAMID COMPANY
1937 West Main Street
P.O. Box 60
Stamford, CT 06904-0060